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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,711	01/24/2000	David S. Roberts	PC10299A	6167

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EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/25/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/489,711	Roberts et al.
Examiner	**Art Unit**
S. Devi, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 30, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *13-30* is/are pending in the application.

4a) Of the above, claim(s) *19-23* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *13-18 and 24-30* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicant's amendment filed 12/30/02 (paper no. 16) in response to the non-final Office Action mailed 08/28/02 (paper no. 14).

Status of Claims

2) Claim 12 has been canceled via the amendment filed 12/30/02.

Claims 13-18 have been amended via the amendment filed 12/30/02.

New claims 24-30 have been added via the amendment filed 12/30/02.

Claims 13-30 are pending.

Claims 13-18 and 24-30 are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

5) The rejection of claim 12 made in paragraph 11 of the Office Action mailed 08/28/02 (paper no. 14) under 35 U.S.C § 102(b) as being anticipated by Sato *et al.* (*Vet. Microbiol.* 43(2): 173-182, 1995 - Applicants' IDS) as evidenced by Petre *et al.* (US 6,013,264, filed 21 May 1993), is moot in light of Applicants' cancellation of the claim.

6) The rejection of claim 12 made in paragraph 12 of the Office Action mailed 08/28/02 (paper no. 14) under 35 U.S.C § 102(b) as being anticipated by Sawada *et al.* (*Am. J. Vet. Res.* 48: 239-242, 1987 - Applicants' IDS) as evidenced by Neurath (US 3,962,421) or Collier *et al.* (US 4,709,017), is moot in light of Applicants' cancellation of the claim.

7) The rejection of claim 12 made in paragraph 13 of the Office Action 08/28/02 (paper no. 14) under 35 U.S.C § 103(a) as being unpatentable over Dayalu *et al.* (WO 91/18627, already of record in view of Sato *et al.* (*Vet. Microbiol.* 43(2): 173-182, 1995 - Applicants' IDS), Wood RL (*J. Am.*

Vet. Med. Assoc. 184: 944-949, 1984, already of record) and Eckhardt *et al.* (US 5,895,655, 11 July 1990), or Barenholz *et al.* (US 6,156,337, 09 September 1996), or Fukuda (US 6,11,089, 28 February 1997), or Volkin *et al.* (US 6,358,744, filed 08 April 1997), is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

8) The rejection of claims 14-16 made in paragraph 12 of the Office Action mailed 08/28/02 (paper no. 14) under 35 U.S.C § 102(b) as being anticipated by Sawada *et al.* (*Am. J. Vet. Res.* 48: 239-242, 1987 - Applicants' IDS) as evidenced by Neurath (US 3,962,421) or Collier *et al.* (US 4,709,017), is withdrawn in light of Applicants' amendment to the claim dependency.

9) The rejection of claims 16-18 made in paragraph 13 of the Office Action 08/28/02 (paper no. 14) under 35 U.S.C § 103(a) as being unpatentable over Dayalu *et al.* (WO 91/18627, already of record) in view of Sato *et al.* (*Vet. Microbiol.* 43(2): 173-182, 1995 - Applicants' IDS), Wood RL (*J. Am. Vet. Med. Assoc.* 184: 944-949, 1984, already of record) and Eckhardt *et al.* (US 5,895,655, 11 July 1990), or Barenholz *et al.* (US 6,156,337, 09 September 1996), or Fukuda (US 6,11,089, 28 February 1997), or Volkin *et al.* (US 6,358,744, filed 08 April 1997), is withdrawn in light of Applicants' amendment to the claim dependency.

10) The rejection of claim 17 made in paragraph 11 of the Office Action mailed 08/28/02 (paper no. 14) under 35 U.S.C § 102(b) as being anticipated by Sato *et al.* (*Vet. Microbiol.* 43(2): 173-182, 1995 - Applicants' IDS) as evidenced by Petre *et al.* (US 6,013,264, filed 21 May 1993), is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

11) The rejection of claims 13 and 16 made in paragraph 11 of the Office Action mailed 08/28/02 (paper no. 14) under 35 U.S.C § 102(b) as being anticipated by Sato *et al.* (*Vet. Microbiol.* 43(2): 173-182, 1995 - Applicants' IDS) as evidenced by Petre *et al.* (US 6,013,264, filed 21 May 1993), is maintained fro reasons set forth therein and herebelow.

Applicants contend that they have deleted the term 'aluminum phosphate' from claim 13 and the amended claim 17 to include the limitation of a stabilizing agent as a part of the vaccine composition. Applicants submit that Sato describes aluminum phosphate to be an adjuvant and that Sato's vaccine is not combined with a stabilizing agent. Applicants state that Sato's reference does

not teach any antigen composition that is stabilized for at least one year at 2 to 8°C and which provides immunity to weaned pigs for six months.

Applicants' arguments have been carefully considered, but are non-persuasive. Contrary to Applicants' assertion, the rejected claims 13 and 16 do not include the limitation that the composition is stable for at least one year at 2 to 8°C and that it elicits immunity to weaned pigs for six months. As far as claim 13 is concerned, the instant invention is still anticipated by Sato *et al.* because Sato's aluminum phosphate meets the claim limitation 'metal phosphate'. With regard to claim 16, the recited fold-concentration is considered as an inherent part of Sato's antigen concentration obtained by ultrafiltration, absent evidence to the contrary.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments and/or submission of new claims.

Rejection(s) under 35 U.S.C. 112, Second Paragraph

12) Claims 16, 28 and 30 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 28 and 30 include the trademark/trade name "Tween 80" and "Span 80". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982)*. The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product and since the composition of the product can change from time to time without any change in the trade name. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe 'Tween 80' and 'Span 80' and, accordingly, the identification/description is indefinite.

(b) Claim 16 is vague in the recitation "...X", because it is not clear what does 'X' stand for.

Rejection(s) under 35 U.S.C. 112, First Paragraph

13) Claims 17 and 29 are rejected under 35 U.S.C § 112, first paragraph, because the specification while being enabling for a vaccine composition comprising about 10X concentrated culture filtrate antigen of *E. rhusiopathiae* produced following formalin or BPL inactivation and combined with about 30% v/v REHYDRAGEL, 10% lecithin in DRAKEOL™ mineral oil, 5.6% Tween 80 and 2.4% Span 80 in PBS provided immunity to weaned pigs after storage at 4°C for at least 6 months, does not reasonably provide enablement for a vaccine composition comprising a concentrated culture fluid fraction of *E. rhusiopathiae* as recited, containing an adjuvant plus any metal hydroxide, any metal phosphate, a calcium phosphate gel, zinc hydroxide/calcium hydroxide gel as a stabilizing agent at any concentration, that is stable for at least one year and that provides immunity to weaned pigs for six months. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims.

The instant claims are evaluated based on the *Wands* analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988)* as follows:

- The quantity of experimentation necessary (time and expense);
- The amount of direction or guidance presented;
- The presence or absence of working examples of the invention;
- The nature of the invention;
- The state of the art;
- The relative skill of those in the art;
- The predictability or unpredictability of the art; and
- The breadth of the claims.

In the instant application, Example 4 is limited to a showing that a vaccine comprising about 10X concentrated culture filtrate antigen of *E. rhusiopathiae* produced following formalin or BPL inactivation and combined with about 30% v/v REHYDRAGEL, 10% lecithin in DRAKEOL™ mineral oil, 5.6% Tween 80 and 2.4% Span 80 in PBS provided immunity to weaned pigs after storage at 4°C for at least 6 months. However, there is no showing that the claimed culture fluid fraction of *E. rhusiopathiae* containing an adjuvant plus any metal hydroxide, any metal phosphate, a calcium phosphate gel, zinc hydroxide/calcium hydroxide gel as a stabilizing agent at any

concentration, remains stable for at least one year and provides immunity to weaned pigs for six months. The antigenic stability and the ability to confer immunity after a year or more of storage of a microbial antigen mixed with any of the broadly recited elements identified above, are not predictable by one of skill in the art. That the composition as recited would have the recited functions or activities would require a concrete demonstration due to this unpredictability factor. Given the lack of such a showing within the instant specification, the lack of direction or guidance, the breadth of the claims, the unpredictability factor, and the quantity of experimentation necessary, undue experimentation would have been required by one of skill in the art at the time the invention was made to reproducibly practice the full scope of invention. The claims are viewed as not meeting the scope of enablement provisions under 35 U.S.C § 112, first paragraph.

Rejection(s) under 35 U.S.C. § 102

14) Claims 13-15 and 24 are rejected under 35 U.S.C § 102(b) as being anticipated by Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-89, 1996) as evidenced by Barenholz *et al.* (US 6,156,337 - already of record).

Zarkasie *et al.* taught a vaccine composition comprising protective antigens of *E. rhusiopathiae* from whole broth culture (therefore culture fluid fraction) and aluminium hydroxide gel, which vaccine conferred various degrees of protection in mice. The antigens are obtained from formalin-inactivated *E. rhusiopathiae* culture (see page 89, right column; Table 2; and pages 87 and 90). That aluminum hydroxide in Zarkasie's composition inherently served as a stabilizing agent is inherent from the teachings of Zarkasie *et al.* in light of what was known in the art. For instance, Barenholz *et al.* taught the dual role of aluminum hydroxide both as an adjuvant and as a stabilizer in microbial vaccines (see column 13, last two lines).

The disclosure of Zarkasie *et al.* anticipates the instant claims. Barenholz *et al.* is **not** used as a secondary reference in combination with Zarkasie *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Zarkasie *et al.* See *In re Samour* 197 USPQ 1 (CCPA 1978).

15) Claims 13, 14 and 24 are rejected under 35 U.S.C § 102(b) as being anticipated by Groschup *et al.* (*Epidemiol. Infect.* 107: 637-49, 1991 - Applicants' IDS) as evidenced by Barenholz *et al.* (US 6,156,337 - already of record).

13, 16

Groschup *et al.* taught an antigenic or vaccine composition comprising a culture supernatant antigen of *E. rhusiopathiae,* obtained from inactivated *E. rhusiopathiae*, which protected mice against *E. rhusiopathiae* infection challenge and which reacted with sera from pigs convalescent from *E. rhusiopathiae* infection. The culture supernatant was filtered and concentrated from 50 ml to a volume of 2 ml. The vaccine having the culture filtrate antigen and contained in aluminum hydroxide conferred protection. See abstract; Table 1; pages 639, 641-643; and page 645.

Claims 13, 14 and 24 are anticipated by Groschup *et al.*

Rejection(s) under 35 U.S.C. 103

16) Claims 13, 16, 17 and 25-27 are rejected under 35 U.S.C § 103(a) as being unpatentable over Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-9, 1996).

The teachings of Zarkasie *et al.* are explained above which do not disclose the additional presence of an adjuvant in their composition, or the final concentration of aluminum hydroxide to be 30% v/v.

However, adding an art-known adjuvant to an art-disclosed microbial vaccine was well known and routinely practiced in the art at the time of the instant invention for the purpose of further enhancing the immunogenicity of a vaccine. Therefore, it would have been *prima facie* obvious to one of skill in the art at the time the invention was made to add an art-known adjuvant to Zarkasie's vaccine composition to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of further improving the immunogenicity of Zarkasie's vaccine composition. With regard to the final concentration of aluminum hydroxide in the antigenic composition and fold-concentration of the fluid fraction, the optimization of concentration of aluminum hydroxide or fluid antigenic fraction is well within the realm of routine experimentation. No evidence is of record in the instant disclosure establishing that the recited final v/v concentration of aluminum hydroxide, or the recited fold-concentration of the fluid fraction is critical to the invention. It has been held legally obvious and within the routine skill in the art to optimize a result effected variable. In the instant case, the final concentration of aluminum hydroxide or the fold-concentration of the fluid antigen in the vaccine composition is clearly a result effected variable in that it is an important component of the

composition, and it would have been obvious to optimize aluminum hydroxide concentration in the composition to 30% v/v, or concentrate the culture fluid to 6 to 20X by routine experimentation.

Claims 13, 16, 17 and 25-27 are *prima facie* obvious over the prior art of record.

17) Claims 13, 16-18 and 28 are rejected under 35 U.S.C § 103(a) as being unpatentable over Dayalu *et al.* (WO 91/18627, already of record) in view of Sato *et al.* (*Vet. Microbiol.* 43(2): 173-182, 1995 - Applicants' IDS), and Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-89, 1996) and Barenholz *et al.* (US 6,156,337, 09 September 1996 - already of record).

The reference of Barenholz *et al.* is applied in this rejection, because it qualifies as prior art under subsection (e) of 35 U.S.C § 102 and accordingly is not disqualified under U.S.C 103(a).

Dayalu *et al.* disclosed a vaccine composition comprising an *Erysipelothrix rhusiopathiae* antigen extract (see page 11; and claims 18 and 19). The vaccine comprised 25% v/v aluminum hydroxide (see page 12), or aluminum hydroxide gel, i.e., stabilizing agent (see page 27, first paragraph). Sterile mineral oil (Drakeol) containing 5 - 40% of lecithin, 0.7 - 32.0% Tween 80, and 0.3 to 1.8% Span, (i.e., adjuvant), were contained in the vaccine composition (see paragraph bridging pages 17 and 18). It is implicit that the percent concentrations of lecithin, oil and amphiphilic surfactant recited in claim 18 fall in the concentration ranges taught by Dayalu *et al.* That aluminum hydroxide intrinsically served as a stabilizing agent in the prior art vaccine is implicit from the teachings of Dayalu *et al.* in light of what was known in the art. For instance, Barenholz *et al.* taught the dual role of aluminum hydroxide both as an adjuvant and as a stabilizer in microbial vaccines (see column 13, last two lines).

Dayalu *et al.* are silent about whether or not the antigen extract is a fluid fraction from the *Erysipelothrix rhusiopathiae* culture.

However, Sato *et al.* taught an antigenic composition comprising a culture filtrate antigen of *Erysipelothrix rhusiopathiae* culture (i.e., fluid fraction). The culture filtrate was fractionated and concentrated by ultrafiltration. The composition was injected into mice. That the process of ultrafiltration concentrates the fluid fraction of the culture by about 6 to about 20-fold is implicit from the teachings of Sato *et al.*

The teachings of Zarkasie *et al.* are explained above, which taught a fluid antigenic fraction of *Erysipelothrix rhusiopathiae*. Zarkasie *et al.* further expressly taught that protective antigens of

Erysipelothrix rhusiopathiae are abundant in the culture filtrate (see page 89, right column), or rich in culture supernatant (see page 90, left column).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the *Erysipelothrix rhusiopathiae* antigen extract in Dayalu's vaccine composition with Sato's culture filtrate antigen of *Erysipelothrix rhusiopathiae* culture (i.e., fluid fraction), to produce the vaccine composition of the instant invention, with a reasonable expectation of success. One skilled in the art would have been motivated to produce the instant invention for the expected benefit of providing, advantageously, a vaccine composition that comprises protective antigens of *Erysipelothrix rhusiopathiae,* because culture filtrate antigens are known in the art to serve as protective antigens as taught by Zarkasie *et al.* Substituting one antigenic composition in a vaccine with another, alternative, art-known antigenic composition that advantageously comprises protective antigens of *Erysipelothrix rhusiopathiae* would have been obvious to one skilled in the art and would have brought about similar, if not better, results.

Claims 13 and 16-18 are *prima facie* obvious over the prior art of record.

18) Claims 17, 28 and 30 are rejected under 35 U.S.C § 103(a) as being unpatentable over Dayalu *et al.* (WO 91/18627, already of record) in view of Groschup *et al.* (*Epidemiol. Infect.* 107: 637-49, 1991 - Applicants' IDS), or Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-89, 1996) and Barenholz *et al.* (US 6,156,337, 09 September 1996 - already of record).

The reference of Barenholz *et al.* is applied in this rejection, because it qualifies as prior art under subsection (e) of 35 U.S.C § 102 and accordingly is not disqualified under U.S.C 103(a).

The teachings of Dayalu *et al.*, Groschup *et al.*, Zarkasie *et al.* or Barenholz *et al.* are explained above.

Dayalu *et al.* are silent about whether or not the antigen extract is a fluid fraction from the *Erysipelothrix rhusiopathiae* culture and do not disclose the specific concentrations of the adjuvant elements or aluminum hydroxide recited in the claims.

However, Zarkasie *et al.* or Groschup *et al.* taught a fluid antigenic fraction of *Erysipelothrix rhusiopathiae*. Zarkasie *et al.* further expressly taught that protective antigens of *Erysipelothrix rhusiopathiae* are abundant in the culture filtrate (see page 89, right column), or rich in culture supernatant (see page 90, left column).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the *Erysipelothrix rhusiopathiae* antigen extract in Dayalu's vaccine composition with Groschup's or Zarkasie's culture filtrate antigen of *Erysipelothrix rhusiopathiae* culture (i.e., fluid fraction), to produce the vaccine composition of the instant invention, with a reasonable expectation of success. One skilled in the art would have been motivated to produce the instant invention for the expected benefit of providing, advantageously, a vaccine composition that comprises protective antigens of *Erysipelothrix rhusiopathiae,* because culture filtrate antigens are known in the art to serve as protective antigens as taught by Zarkasie *et al.* Substituting one antigenic composition in a vaccine with another, alternative, art-known antigenic composition that advantageously comprises protective antigens of *Erysipelothrix rhusiopathiae* would have been obvious to one skilled in the art and would have brought about similar, if not better, results. With regard to the specific concentrations of adjuvant elements or of aluminum hydroxide, the optimization of concentrations of adjuvant elements or aluminum hydroxide is well within the realm of routine experimentation. No evidence is of record in the instant disclosure establishing that the recited concentrations of adjuvant elements or aluminum hydroxide are critical for the invention. It has been held legally obvious and within the routine skill in the art to optimize a result effected variable. In the instant case, the concentrations of adjuvant elements or of aluminum hydroxide in the vaccine composition are clearly result effected variables, and it would have been obvious to optimize their concentrations in the composition as recited by routine experimentation.

Claims 17, 28 and 30 are *prima facie* obvious over the prior art of record.

Remarks

19) Claims 13-18 and 24-30 stand rejected.

20) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the

date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

22) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER